REVIEW OF THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR PARTICULATE MATTER:

POLICY ASSESSMENT OF SCIENTIFIC AND TECHNICAL INFORMATION

I. PURPOSE

The purpose of this Office of Air Quality Planning and Standards (OAQPS) Staff Paper is to evaluate the policy implications of the key studies and scientific information contained in the EPA document, "Air Quality Criteria for Particulate Matter" (U.S. EPA, 1996, henceforth referred to as the CD), and to identify the critical elements that EPA staff believes should be considered in review of the national ambient air quality standards (NAAQS) for particulate matter (PM). This assessment is intended to help bridge the gap between the scientific review contained in the CD and the judgments required of the Administrator in setting ambient standards for PM. Thus, emphasis is placed on identifying those conclusions and uncertainties in the available scientific literature that the staff believes should be considered in selecting particulate pollutant indicators, forms, averaging times, and levels for the primary (health) and secondary (welfare) standards. These specifications must be considered collectively in evaluating the health and welfare protection afforded by PM standards.

While this Staff Paper should be of use to all parties interested in the standards review, it is written for those decision makers, scientists, and staff who have some familiarity with the technical discussions contained in the CD. This Staff Paper presents factors relevant to the evaluation of current primary and secondary NAAQS, as well as staff conclusions and recommendations of suggested options for the Administrator to consider.

II. BACKGROUND

A. Legislative Requirements

Two sections of the Clean Air Act govern the establishment and revision of NAAQS (42 U.S.C. 7401 to 7671q, as amended). Section 108 (42 U.S.C. 7408) directs the Administrator to identify pollutants which "may reasonably be anticipated to endanger public health and welfare" and to issue air quality criteria for them. These air quality criteria are intended to "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in the ambient air . . ."

Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate "primary" and "secondary" NAAQS for pollutants identified under section 108. Section 109(b)(1) defines a primary standard as one "the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health."[1] A secondary standard, as defined in section 109(b)(2), must "specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air." Welfare effects as defined in section 302(h) [42 U.S.C. 7602(h)] include, but are not limited to, "effects on soils, water, crops, vegetation, manmade [sic] materials, animals, wildlife, weather, visibility and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being."

The U.S. Court of Appeals for the District of Columbia Circuit has held that the requirement for an adequate margin of safety for primary standards was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection

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[1]The legislative history of section 109 indicates that a primary standard is to be set at "the maximum permissible ambient air level … which will protect the health of any [sensitive] group of the population," and that for this purpose "reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group" (S. Rep. No. 91-1196, 91st Cong., 2d Sess. 10 (1970)).

against hazards that research has not yet identified (*Lead Industries Association v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir. 1980), cert. denied, 101 S. Ct. 621 (1980); *American Petroleum Institute v. Costle*, 665 F.2d 1176, 1177 (D.C. Cir. 1981), cert. denied, 102 S. Ct. 1737 (1982)). Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, by selecting primary standards that provide an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that she finds may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree.

In selecting a margin of safety, the EPA considers such factors as the nature and severity of the health effects involved, the size of the sensitive population(s) at risk, and the kind and degree of the uncertainties that must be addressed. Given that the "margin of safety" requirement by definition only comes into play where no conclusive showing of adverse effects exists, such factors which involve unknown or only partially quantified risks have their inherent limits as guides to action. The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment (*Lead Industries Association v. EPA*, supra, 647 F.2d at 1161-62).

Section 109(d)(1) of the Act requires that "not later than December 31, 1980, and at 5-year intervals thereafter, the Administrator shall complete a thorough review of the criteria published under section 108 and the national ambient air quality standards … and shall make such revisions in such criteria and standards … as may be appropriate …." Section 109(d)(2) requires that an independent scientific review committee be appointed and provides that the committee "shall complete a review of the criteria … and the national primary and secondary ambient air quality standards … and shall recommend to the Administrator any … revisions of existing criteria and standards as may be appropriate …." Since the early 1980's, this independent review function has been performed by the Clean Air Scientific Advisory Committee (CASAC) of EPA's Science Advisory Board.

B. History of PM NAAQS Reviews

1. Establishment of the NAAQS for Particulate Matter

National ambient air quality standards for PM were first established in 1971, based on the original criteria document (DHEW, 1969). Particulate matter is the generic term for a broad class of chemically and physically diverse substances that exist as discrete particles (liquid droplets or solids) over a wide range of sizes. Particles originate from a variety of anthropogenic stationary and mobile sources as well as natural sources. Particles may be emitted directly or formed in the atmosphere by transformations of gaseous emissions such as sulfur oxides, nitrogen oxides, and volatile organic substances. The chemical and physical properties of PM vary greatly with time, region, meteorology, and source category, thus complicating the assessment of health and welfare effects.

The reference method specified for determining attainment of the original standards was the high-volume sampler, which collects PM up to a nominal size of 25 to 45 micrometers (μm) (so-called total suspended particulate or TSP). The primary standards (measured by the indicator TSP) were 260 micrograms per cubic meter ($\mu g/m^3$), 24-hour average, not to be exceeded more than once per year, and 75 $\mu g/m^3$, annual geometric mean. The secondary standard (measured as TSP) was 150 $\mu g/m^3$, 24-hour average, not to be exceeded more than once per year.

2. First Review of NAAQS for Particulate Matter

In October 1979 (44 FR 56731), EPA announced the first review of the criteria document and NAAQS for PM and, after a lengthy and elaborate process, promulgated significant revisions of the original standards in 1987 (52 FR 24854, July 1, 1987).[2] In that decision, EPA changed the indicator for particles from TSP to PM_{10}, the latter referring to particles with a mean aerodynamic diameter less than or equal to

[2]The revised standards were based on a revised Criteria Document (U.S. EPA, 1982a), a corresponding Staff Paper (U.S. EPA, 1982b), and subsequent addenda to those documents (U.S. EPA, 1986a; U.A. EPA, 1986b). A detailed description of the process followed in reviewing and revising the original Criteria Document and NAAQS appears in the notice of final rulemaking (52 FR at 24636-37).

10 μm.[3] EPA also revised the level and form of the primary standards by 1) replacing the 24-hour TSP standard with a 24-hour PM_{10} standard of 150 $\mu g/m^3$ with no more than one expected exceedance per year and 2) replacing the annual TSP standard with a PM_{10} standard of 50 $\mu g/m^3$, expected annual arithmetic mean. The secondary standard was revised by replacing it with 24-hour and annual standards identical in all respects to the primary standards. The revisions also included a new reference method for the measurement of PM_{10} in the ambient air and rules for determining attainment of the new standards. On judicial review, the revised standards were upheld in all respects (Natural Resources Defense Council v. Administrator, 902 F. 2d 962 (D.C. Cir. 1990), cert. denied, 111 S. Ct. 952 (1991)).

3. Recent Litigation

The American Lung Association filed suit in February l994 to compel EPA to complete the present review of the PM NAAQS by December l995. The U.S. District Court for the District of Arizona subsequently ordered EPA to complete its review and any revision of the PM NAAQS by publishing a final decision in the Federal Register by January 31, l997, with publication of a proposed decision required by June 30, l996 (American Lung Association v. Browner, CIV-93-643-TUC-ACM (D. Ariz., October 6, l994)). As subsequently modified, the court-ordered schedule requires publication of the proposed and final decisions by November 29, l996, and June 28, l997, respectively.

4. Current Review of the Particulate Matter NAAQS

In December 1994, EPA presented its plans for completing review of the criteria document and NAAQS for PM under the court order to the CASAC. In addition, EPA's OAQPS completed a PM NAAQS Development Project Plan in January 1995, which incorporated CASAC comments, identifying key issues to be addressed in this Staff Paper

[3]The more precise term is 50 percent cut point or 50 percent diameter (D_{50}). This is the aerodynamic particle diameter for which the efficiency of particle collection is 50 percent. Larger particles are not excluded altogether, but are collected with substantially decreasing efficiency and smaller particles are collected with increasing (up to 100 percent) efficiency. Ambient samplers with this cut point provide a reliable estimate of the total mass of suspended particulate matter of aerodynamic size less than or equal to 10 μm.

as well as the basis for the additional scientific and technical assessments needed to address the policy issues.

EPA desires to incorporate as much peer review and public input into the review as is possible under the court-ordered schedule. Accordingly, as part of the development of the CD, EPA hosted a public PM-Mortality Workshop in November 1994, at which seminal new studies on particles and health effects were presented and discussed. In January 1995, the EPA's National Center for Environmental Assessment (NCEA) hosted three public peer-review workshops on drafts of key chapters of a revised CD.

Successive external review drafts of the revised CD were reviewed by CASAC and the public at public meetings held on August 3-4, 1995 and December 15-16, 1995. The first external review draft of this Staff Paper was also reviewed by CASAC and the public at the December 16, 1995 meeting. Based on CASAC and public comment, NCEA revised the CD and submitted chapters the committee had requested for additional review (namely CD chapters 1, 5, 6, and 13) to CASAC and the public for review at a public meeting held February 29, 1996. At this meeting, CASAC also discussed the plan and methodologies for the risk assessment presented in this Staff Paper. On March 15, 1996, CASAC sent a letter to the EPA Administrator indicating the committee's satisfaction with the CD (Wolff, 1996b). NCEA made additional revisions to the document to respond to comments from CASAC and the public and completed the CD on April 12, 1996. At a public meeting held on May 15-16, 1996, CASAC and the public reviewed the revised Staff Paper, provided additional comments, and came to closure on the document. On June 13, 1996, CASAC sent a closure letter on the Staff Paper to the EPA Administrator (Wolff, 1996c). Both CASAC closure letters are reproduced in Appendix G of this Staff Paper.

III. APPROACH

This Staff Paper is based on the scientific evidence reviewed in the CD and takes into consideration CASAC and public comments received on the previous drafts. The staff has also considered comparative air quality and quantitative risk analyses in evaluating the appropriateness of retaining or revising the current primary NAAQS and in assessing potential alternative NAAQS. Technical and economic analyses examining visibility impairment and soiling and materials damage have also been considered in evaluating the appropriateness of retaining or revising the current secondary NAAQS and in assessing potential alternative NAAQS.

The approach taken in this Staff Paper is to assess and integrate the above information in the context of those critical elements that the staff believes should be considered in reviewing the primary and secondary standards. Attention is drawn to judgments that must be made based on careful interpretation of incomplete or uncertain evidence. In such instances, the Staff Paper provides the staff's evaluation, sets forth alternatives the staff believes should be considered, and recommends a course of action.

A. Bases for Initial Analytical Assessments

The staff identified several possible policy alternatives to provide a basis for commencing initial analytical assessments of air quality, human exposure, and health risks. 1.

Primary Standards

As in the 1987 review of the NAAQS, selecting the most appropriate indicator for PM is a major issue for this review. Thus, the staff planned for initial analytic assessments of the assumption that this PM NAAQS review might result in setting or retaining one or more primary standards from the following possibilities:

- Short-term Standard: A 24-hour standard using a fine particle indicator, a PM_{10} indicator, or both; and

- Long-term Standard: An annual standard using a fine particle indicator, a PM_{10} indicator, or both.

The staff also recognized that other indicators of PM pollution (e.g., sulfates and acids) may be important in relating effects to PM pollution.

2. Secondary Standards

In revising the secondary standards, the staff has focused primarily on two types of effects: 1) visibility impairment and 2) soiling and materials damage. In the case of visibility, this Staff Paper briefly assesses available scientific information in order to determine an appropriate regulatory approach for addressing regional haze. A key consideration in this assessment is that a number of factors that influence visibility impairment vary significantly between the eastern and western parts of the U.S. Thus, this Staff Paper examines the advisability of a uniformly implemented and attained secondary NAAQS as contrasted to the establishment of a regional haze program under section 169A of the Clean Air Act. This Staff Paper also examines the available literature on material damage and soiling to ascertain whether such information provides a basis for establishing a separate national secondary NAAQS to protect against such effects.

B. Organization of Document

The remainder of this Staff Paper is organized as outlined below. Chapter IV summarizes differences among the various fractions of PM_{10}, air quality trends for both PM_{10} and fine particles, characterizations of average "background" concentrations, information on relationships between PM and population exposures, and the air quality implications of ongoing PM control programs designed to attain the current PM NAAQS.

Chapter V discusses available information on PM dosimetry and hypotheses regarding mechanisms of toxicity, the nature of health effects associated with PM, sensitive subpopulations, and integrated evaluations of the scientific evidence. Chapter V also presents alternative interpretations of the evidence and uncertainties surrounding reported health effects associations and specific agents of concern which are important for the Administrator to consider in selecting appropriate primary standards.

Chapter VI summarizes health risk assessments conducted for two urban areas to provide quantitative estimates of the risks to public health associated with 1) existing PM air quality levels, 2) projected air quality levels that would occur upon attainment of the current PM_{10} standards, and 3) projected air quality levels associated with attainment of alternative $PM_{2.5}$ standards.

Drawing on these factors and on information contained in the previous chapters, Chapter VII presents staff conclusions and recommendations for the Administrator to consider in reaching decisions on the retention and/or revision of the primary NAAQS. The chapter addresses alternative pollutant indicators, averaging times, forms, and levels, with summary sections highlighting both key uncertainties and related staff research recommendations as well as staff's overall recommendations for a suite of primary standards.

With respect to review of the secondary standards, Chapter VIII presents information on visibility impairment and soiling and materials damage, discusses pertinent scientific, technical, and policy considerations, and offers staff conclusions and recommendations for the Administrator to consider in reaching a decision on retention and/or revision of the secondary NAAQS.